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[Notices]

[Pages 28014-28018]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2009-1005; FRL-8824-4]

Petitions Concerning Whether Ammonia or Urea Sold or Distributed
and Used for Certain Purposes Should Be Regulated as Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice makes available for review and public comment three petitions concerning the regulatory status under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) of products containing ammonia or urea sold or distributed for use in the presence of sodium hypochlorite as a biocide or as part of a biocidal system in the production of pulp and paperboard products. The notice also makes available for review and public comment documents associated with the petitions which have also been placed in a docket created for this matter. That docket may be accessed as described in this Notice. The Agency registered as ``pesticides'' two products containing ammonia as the active ingredient based on applications for registration and supporting data submitted by Buckman Laboratories, Inc. (Buckman). The Agency has also registered an ammonium bromide product for a similar use in the pulp and paperboard industry. Another company, Nalco, Inc. (Nalco) is currently selling unregistered ammonia and urea products to the pulp and paperboard industry for use in a manner similar to those of the three registered products. Nalco informed EPA of its view that Buckman's ammonia products were not ``pesticides'' and argued therefore that EPA should not have registered them under FIFRA. Nalco petitioned the Agency to cancel Buckman's registrations for the two ammonia products. Subsequently, the Agency received two other petitions from Buckman and Ashland Hercules Water Technologies (Ashland-Hercules), which would also be affected by any Agency decision relative to the contested uses of ammonia and urea, supporting the decision to register ammonia and further requesting that the Agency find Nalco's sale and distribution of its unregistered ammonia product to be contrary to law. Ashland-Hercules also raised issues relative to the safe use and risks associated with the unregistered use of urea in chlorinated water in pulp and paper mill use scenarios and asked that the Agency find that Nalco's sale and distribution of its urea product was unlawful.

DATES: Comments must be received on or before July 19, 2010.

ADDRESSES: Submit your comments identified by the docket identification (ID) number EPA-HQ-2009-1005, by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the on-line instructions for submitting comments.

Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

Delivery: OPP Regulatory Public Docket (7502P),

Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to the docket ID number EPA-HQ-2009-1005. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an ``anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

[[Page 28015]]

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: For general information contact: Melba S. Morrow, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-2716; fax number: (703) 308-6467; e-mail address: morrow.melba@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a business engaged in the manufacturing of pesticides and other agricultural chemicals. Potentially affected entities may include, but are not limited to:

Pesticide and other agricultural and chemical manufacturing (NAICS code 325320) e.g. businesses engaged in the manufacture of pesticides.

Pulp and paperboard industries (NAICS code 322110, 322130).

Antimicrobial pesticides (NAICS code 32561).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected. The North American Industrial Classification System codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity please contact the person list under FOR FURTHER INFORMATION CONTACT.

B. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree with any of positions taken in the petitions; suggest alternatives and substitute language for your requested changes. Carefully consider the merits of what you are proposing.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient details to allow it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest appropriate alternative measures when possible.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline that has been identified.

3. Environmental justice. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. Legal Authority

Under FIFRA and its regulations, no person may distribute or sell any pesticide product that is not registered under the Act except as provided under 40 CFR 152.20, 152.25 and 152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest, among other things. The regulations in 40 CFR 152.15 contain provisions that guide the Agency's determination of

whether a particular product is a ``pesticide'' under FIFRA.

FIFRA also provides the Agency with authority to cancel or suspend pesticides which do not comply with the Act or no longer meet the statutory standard for registration. FIFRA further authorizes the Agency to initiate enforcement action against persons who are not in compliance with the Act. Enforcement actions may, among other things, be initiated on the basis of sale or distribution of unregistered pesticide products or unlawful use of a registered pesticide product. See generally, FIFRA Sections 3, 6, 12, and 13.

III. History of Registrations for Ammonia and Urea Products for Use in the Pulp and Paper Industry

Buckman is the registrant of BCMW (EPA Reg. No. 1448-432) and Busan 1215 (EPA Reg. No. 1442-433). Both products were registered in 2007, and both products contain ammonia as the active ingredient. Buckman's ammonia products are registered for use as a water treatment in combination with sodium hypochlorite to inhibit the growth of bacteria in pulp and paper mills. Ashland-Hercules is the authorized distributor of Spectrum XD3899 Ammonium Bromide Technology (EPA Reg. No. 8622-64-74655), an ammonium bromide solution sold as a FIFRA Section 3(e) supplemental distributor product under Ameribrom, Inc.'s Fuzzicide Solution (EPA Reg. No. 8622-64) that was registered in 2003. Nalco does not hold any registrations for ammonia or urea products for use in pulp and paper mills. Nalco is currently marketing and distributing their ammonia product, Nalcon 60620, that is used in combination with sodium hypochlorite. Nalco is also marketing and distributing a urea-based product, Nalcon 60615, which is also used as a water treatment for the production of biocides in pulp and paper mill settings.

[[Page 28016]]

IV. Summary of the Petitions and Other Documents

The Agency has received petitions and multiple related submissions from Ashland-Hercules, Buckman, and Nalco regarding the regulatory status of products containing ammonia or urea when intended for use in the presence of sodium hypochlorite as a biocide or as part of a biocidal system in the production of pulp and paperboard products. The submissions from Nalco generally argue that under FIFRA, those products are not ``pesticides'' when used under that circumstance. The submissions provided by Ashland-Hercules and Buckman argue that these products when intended or used for such purpose are ``pesticides'' requiring registration under FIFRA. The history of each petition and the principal arguments are summarized below.

A. Nalco, Inc.

Nalco filed a petition on October 30, 2007 and requested that EPA revisit the requirement to register ammonia as a pesticide under FIFRA. The petitioner acknowledged the Agency had issued registrations for products containing ammonia to be used to inhibit the growth of bacteria in water used in pulp and paper mills. In its discussion of current biocidal control practices in the manufacture of pulp and paperboard products, the petitioner explained that it is common practice to add ammonia-based products to water which has been treated with chlorine in order to generate chloramines. Nalco further contended that, by requiring registration of ammonia, all companies that currently provide unregistered ammonia products for use with chlorine in water treatment are in violation of FIFRA. The Nalco petition stated that, in requiring the registration of ammonia, the Agency had failed to assess the impact that such a requirement would have on the regulated community. According to Nalco, EPA's decision to register ammonia products intended for use as part of a biocidal system in the production of pulp and paperboard products represented a change in

EPA's policy that was undertaken without an opportunity for public input. The Nalco petition further stated that requiring registration of ammonia would in essence require that all users purchase ammonia from the only EPA-registered source. The Nalco petition requested that the Agency issue an interim statement that the sale of ammonia-based compounds for use with chlorine in water systems would not result in enforcement action and that the Agency would reconsider whether companies need to register ammonia when intended for use as part of a biocidal system in the production of pulp and paperboard products. The petition also argued that the decision to require the registration of ammonia products would also have an impact on municipal water treatment facilities, as the practice of adding ammonia is necessary to produce chloramines for municipal water disinfection.

On December 4, 2007, Nalco wrote the Agency asking EPA to reconsider earlier actions requiring the registration of ammonia, which Nalco described as a ``precursor'' to chloramine in water treatment processes, and to assure Nalco that there would be no enforcement action taken during the transition period. The December 4 Nalco submission made the following assertions and arguments:

As shown in the background information on the chemistry of chlorine in antimicrobial water treatment, chloramines are weak biocides. Because they are more stable than chlorine, chloramines are used in water systems to extend the period of antimicrobial activity and to minimize the production of other by-products of water disinfection by reducing the reactivity of chlorine.

Ammonia is not a pesticide and does not contribute to the pesticidal activity of sodium hypochlorite or other chlorine-based water disinfectants. In industrial water systems such as those used by pulp and paper mills, there is high organic content in the water systems which can be controlled through the generation of chloramines. Chloramines reduce disinfection demands. The pesticidal activity of chloramine is a result of the residual activity of chlorine.

Chlorine is the active ingredient in water treatment and the reaction with ammonia only stabilizes or sequesters ammonia. Thus, ammonia is not a precursor for in situ generation of a pesticide. Moreover, even if ammonia were a precursor, the Agency's decision to register ammonia is inappropriate because in the past, EPA has registered precursors when they are the only logical chemical through which the use of a pesticide can be regulated. Prior to the registration of ammonia for use as part of a biocidal system in the production of pulp and paperboard products, the Agency never required registration of ammonia compounds.

Rather than designating ammonia as a ``precursor,'' EPA should consider it a ``stabilizer'' or an ``activator.'' The Agency's historical position has been that activators need not be registered. The Agency's decision to require the registration of ammonia is also inconsistent with the Agency's position on other chemicals, such as cyanuric acid used to stabilize chlorine in swimming pools, which performs similar functions. The submission contained an Appendix listing inert ingredients found in other pesticides that allegedly play a role similar to ammonia.

The Agency should articulate a rule of decision regarding when registration is required and assess the impact of that rule before it is implemented. The rationale for a decision to require registration of ammonia should also be articulated. The current situation, in which one registrant of ammonia is threatening enforcement against users of similar systems in pulp and paper mills using unregistered ammonia compound, is causing confusion in the marketplace.

In follow-up to the December submission, on February 7, 2008, EPA sent Nalco a letter indicating that the December 4th communication would be treated as a petition. The letter further stated ``...the Office of Pesticide Programs would regard Nalco's sale and distribution of ammonia and ammonia products for use in connection with chlorine to treat water to require registration under FIFRA Section 3 only if Nalco makes a pesticidal claim for such products.'' In July 2008, the Agency

asked Nalco to define the term ``activator'' and to provide further explanation of the relationship between ammonia and the inert ingredients listed in the appendix to the December submission.

In July 2008, Nalco filed a supplement to its December 2007 submission. Nalco acknowledged that there is no regulatory definition of an activator and stated its opinion that ammonia is merely a ``stabilizer'' which acts to prolong the availability of chlorine, and would therefore not meet the definition of a pesticide. Nalco further characterized ammonia as a ``sequestrant'', and defined that term as a substance which acts by preventing or inhibiting normal ion behavior by combination with added materials. In reference to the compounds identified in an appendix to Nalco's December 2007 submission, Nalco stated that they were included as examples of available compounds that have been determined by the Agency to be inert compounds. The description of the purpose of the inert component indicates that it will modify the activity of or interact with the pesticidally active ingredient in the formulation. Nalco compared the role of the inert compounds to that of ammonia by stating that the description of the inert compounds suggests a chemical

[[Page 28017]]

reaction but not one that is needed to produce a pesticidally active ingredient.

B. Buckman Laboratories, Inc.

Buckman filed its petition on September 2, 2008, and responded to the concerns raised by Nalco's petition. Buckman defended the status of its ammonia products as registered pesticides and requested that the Agency immediately prohibit further distribution and sale of unregistered ammonia for water treatment. In addition, Buckman provided information on the chemical reaction which results in the formation of chloramines following the addition of ammonia to chlorinated water. Buckman stated in its petition that ammonia does not sequester or release chlorine and is not an adjuvant. Buckman further contended that ammonia reacts with sodium hypochlorite to produce an entirely new active ingredient, monochloramine (MCA), which has distinct biocidal properties. Buckman stated its opinion that the MCA, which is created by the chemical reaction, ``is the main active ingredient'' for biocidal water treatment in the pulp and paper process.

Buckman provided the following rationale to support its request that the Agency maintain the status quo, i.e., its position that products containing ammonia intended for use in the presence of sodium hypochlorite as a biocide or as part of a biocidal system in the production of pulp and paperboard products are pesticides requiring registration under FIFRA. Buckman repeated its request that EPA prohibit further distribution and sale of unregistered ammonia products. Buckman's main points were:

Both Nalco and Buckman sell ammonia for use in proprietary systems in which ammonia and sodium hypochlorite react to form monochloramine, which is the active ingredient supplied by each system for water treatment. The basic chemistry involving both the Nalco and Buckman products and the production of MCA is the same.

The registration of ammonia is necessary because monochloramine is too unstable to exist as a marketable commodity, and no EPA-approved sodium hypochlorite label has instructions for use with ammonia to result in the safe production of MCA. In addition, the continued use of unregistered ammonia to produce MCA poses a potentially unreasonable risk to human health and the environment. There is no way to ensure that the MCA produced with an unapproved product will result in acceptable residues in food packaging or not pose a risk of toxicity to aquatic organisms from the residues in the effluent.

Ammonia does not sequester or release chlorine and is not

an adjuvant. Ammonia reacts with sodium hypochlorite to produce MCA which has distinct properties (the mechanism by which it inactivates microorganisms by adversely affecting cell respiration, transport and DNA activity; a different spectrum of antimicrobial activity) from hypochlorous acid.

The Agency should deny Nalco's petition to revoke Buckman's ammonia registrations because the Agency has acted properly in its registration of ammonia as a precursor to the formation of MCA for water treatment. As a precursor of MCA, ammonia reacts with sodium hypochlorite to produce a new active ingredient, which has distinct properties as described above.

The Agency should prohibit further distribution and sale of unregistered ammonia for water treatment because the continued sale of unregistered ammonia presents an unreasonable risk to public health and unfairly damages the commercial value of Buckman's registrations.

C. Ashland-Hercules

Ashland-Hercules contacted the Agency in February 2009 with a petition that also included a file of correspondence to and from the Agency that dated back to June 2008. Ashland-Hercules's arguments were basically the same as those provided by Buckman with regard to Nalco's distribution and sale of unregistered ammonia for use with sodium hypochlorite as a biocide or as part of a biocidal system in the production of pulp and paperboard products. Ashland-Hercules further discussed the need for the Agency to take action against the sale or distribution of unregistered urea products as biocidal agents in the pulp and paperboard industry. Ashland-Hercules based this on arguments that urea has not been subjected to review for registration as an antimicrobial pesticide as required under FIFRA. Ashland-Hercules stated that the use of an unregistered urea-based product presents potential risks to human health and safety that EPA has not evaluated. Ashland-Hercules made the following points:

There is a distinction between the treatment of public potable water supplies with MCA and the application of ammonia in the presence of sodium hypochlorite to prevent biofouling in the paper industry. Although the two uses are conceptually similar, the concentrations at which ammonia and chlorine are used are not the same.

The potential hazards presented by the unregulated and uncontrolled use of ammonia-based biocides in pulp and paper mills are far greater than those associated with potable water treatment because of higher concentrations of chemicals that are used for biocidal activity in pulp and paper mills, thereby exposing workers to increased risks.

While ammonia-based products used in treating potable water may not be registered under FIFRA, EPA has regulated chloramines produced by the addition of ammonia to chlorine under the Safe Drinking Water Act (SDWA). Thus, there is a basis for assuring the safety of potable water using the authority of the SDWA. The same can not be said for Nalco's product.

The chemical reaction that takes place when concentrated ammonia-based compounds are combined in situ with concentrated sodium hypochlorite can result in the release of hazardous gases such as nitrogen trichloride and raises safety concerns when using Nalco's product.

An unregistered product has no upper limits for feed rates. The exposure to the undesirable compounds produced during the uncontrolled mixing of concentrated solutions of ammonium sulfate and sodium hypochlorite is unlimited as well.

D. Current Status

The Agency believes that all three parties have raised matters which pose common issues and which therefore are being considered and addressed together. The Agency's Office of Pesticide Programs, which is

leading this effort to consider these petitions, is also examining other issues, including any potential issues involving EPA's Office of Water and is obtaining information for use in making its decision on whether the sale and distribution of ammonia and urea products for use with chlorine-treated water in pulp and paper production are pesticidal uses that require registration under FIFRA.

EPA held a meeting on February 16, 2010 with all of the parties who either hold registrations for ammonia or who had petitioned the Agency with concerns pertaining to the status of the ammonia or urea products described above. The materials from the meeting as well as a transcript of the meeting have been placed in the docket, along with the three petitions, and correspondence associated with the petitions.

[[Page 28018]]

V. What Action is the Agency Taking

Through this notice, the Agency is making the petitions and other correspondence submitted by Nalco, Buckman Laboratories and Ashland Hercules available for public review and comment. Any public comments received on these petitions will be included in the electronic docket and reviewed by the Agency. Following review of the petitions and any comments received in response to this notice, EPA will issue its decision and response to the petitions.

In reviewing the materials in the docket and submitting any comments to the Agency, the Agency requests that, in addition to providing comments regarding any other issues raised by the materials in the docket, commenters respond to the following specific questions:

When the ingredients in a product do not provide any pesticidal activity unless they react with other chemicals, should the product be treated as a pesticide? Are there any other factors which could or should lead to a different outcome in different settings? If so, what are they and what would the different outcome be?

When a product is marketed as an essential part of a system or as a co-ingredient in a treatment regime that provides a pesticidal function, should the product be registered as a pesticide? Should the system be registered as a pesticide product? Are there any other factors which could or should lead to a different outcome in different settings? If so, what are they and what would the different outcome be?

If a system is registered as a pesticide, how should requirements governing labeling and compositions apply to the system and to individual products comprising the system?

What are the implications for other products containing ammonia or urea that are used in conjunction with chlorine-treated water in settings other than the production of pulp and paperboard?

What substances, other than ammonia or urea, are sold for uses similar to the Ashland, Buckman, and Nalco products, and might require registration or might currently be registered?

List of Subjects

Environmental protection, Pesticides and pests.

Dated: May 3, 2010.

Joan Harrigan-Farrelly,
Director, Antimicrobial Division, Office of Pesticide Programs.
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